

HOLE-FORMING PIN FOR INSERTING INDWELLING NEEDLE AND JIG FOR INSTALLING THE PIN

5 Technical Field

The present invention relates to a pin for forming an insertion hole from a skin surface of a human body to the wall of a blood vessel or to a position close to the wall for inserting ~~a dwelling~~an indwelling needle, and a jig for installing the pin.

10 Background Art

In general, a hemodialysis patient needs to be subjected to hemodialysis at a rate of twice to ~~three time~~three times a week, and puncturing of the indwelling needle causes the patient to experience considerable pain every time.

Therefore, in order to minimize the puncturing pain, the applicant has already proposed a hole-forming pin for inserting an indwelling needle (See Publication of Design Registration No. 1136452, No.1137743, No.1138667, No.1140738). These hole-forming pins each comprises a columnar insertion part having a rounded distal end and an insertion stop part provided at the proximal end of the insertion part, and a holding part (recess) provided on the insertion stop part to which the distal end of an insertion assisting device is inserted to retain the pin.

When the pin for forming a hole for inserting an indwelling needle is inserted from a skin surface of a human body to the wall of a blood vessel or to a position close to the wall and left for several days, a hole (hereinafter referred to as a "buttonhole") is formed as

a passage for inserting the indwelling needle. After the puncturing, puncturing pain that is caused on puncturing with a method other than this buttonhole-puncturing method can be significantly alleviated since the indwelling needle can be inserted through this buttonhole.

However, the conventional hole-forming pin for inserting an indwelling needle has
5 a spherical shape, conical shape, egg shape, or flat shape with a ~~not so large~~ small contact area ~~to~~ with the skin as the shape of the insertion stop part-form, and fixation is not necessarily perfect in indwelling.

For example, in the worst case such that an excessive load is applied to a body (button
10 hole) with the slightest of opportunities as in the case of ~~a~~ touching contacting something and the like, there may be ~~eases~~ a case that a button hole ~~are~~ is formed in ~~the~~ a direction other than the direction ~~to~~ of the blood vessel in a state in which the ~~swinged~~-insertion part ~~are~~ is fixed, or a case that a button hole cannot be formed at all with ~~the~~-detaching of the hole-forming pin.

15 The conventional insertion assisting device for holding the pin for forming a pin for inserting an indwelling needle described above has problems in operability such that it is difficult to check ~~out~~ the direction of fitting of the pin, or that the pin itself cannot be removed easily from the insertion assisting device.

20 Disclosure of the Invention

In view of such circumstances, it is an object of the present invention to provide a hole-forming pin which can be inserted easily into a puncture passage immediately after

removing a dialysis indwelling needle and which can prevent ~~the-a~~ button hole from being formed in ~~the directions-a direction~~ other than the direction toward the blood vessel or from being disconnected easily against the operator's will so as to minimize a load to a living body. ~~And it~~ It is also an object of the present invention to provide a jig for installing the
5 hole-forming pin (insertion assisting device) with good operability.

As the result of intense study ~~aiming to solve~~aimed at solving—the above-described problems, the present inventors have found that by providing wings on the pin for forming a hole for inserting an indwelling needle, an inserting operation can be performed easily
10 because the operator can hold the wings for inserting the hole-forming pin into the puncture passage. The present inventors have also found that by fixing the wings with adhesive tape or the like during indwelling, the direction of formation of the button hole can be prevented from changing. The present inventors have further found that by providing elastic joint parts at connecting parts between the wings and the insertion stop part, fine adjustment of
15 the angle of insertion of the insertion part is achieved and hence a load exerted on the living body can be minimized. ~~The present inventors have found that consequently reached the present invention.~~ Also, the present inventors have achieved a jig from which the hole-forming pin can be removed ~~at a good timing simultaneously with fitting by insertion~~ of the hole-forming pin from the skin surface.

20 In other words, the hole-forming pin for inserting an indwelling needle of the present invention is a pin for forming a buttonhole from a skin surface to a blood vessel to indwell an indwelling needle. The hole-forming pin for inserting an indwelling needle

comprises a column-shaped insertion part having a curved surface at the distal end thereof, an insertion stop part provided at the proximal end of the insertion part, and wings connected to the insertion stop part, wherein the insertion stop part and the wings are connected through ~~a~~an elastic joint.

5 Therefore, although an insertion assisting device to retain ~~the~~a hole-forming pin for inserting ~~the~~an indwelling needle was necessary and a troublesome operation to set the insertion assisting device ~~in~~at the angle of insertion and ~~bring~~removing the hole-forming pin ~~apart~~ from the insertion assisting device was necessary in the prior art, ~~according to~~, since according to the present invention the operator can hold and insert the wing part 10 with fingertips and fix the same in the inserted state, the hole-forming pin for inserting an indwelling needle of the present invention ~~have~~has the effect that the indwelling operation can be performed easily.

15 In the hole-forming pin for inserting an indwelling needle of the present invention, the outer diameter of the insertion part is from 0.5 to 3.0 mm and the length of the insertion part is from 3 to 20 mm.

In other words, although the diameter is determined by the size of the puncture passage immediately after removal of the dialysis-indwelling needle, it is preferable that the 20 diameter is from about 1.5 mm to 3 mm ~~in consideration of~~considering the general needle diameter ~~that is~~of from 1.2 mm to 1.8 mm (from 1.5 to 2.3 mm for plastic ~~needl~~needles). In addition, the hole-forming pin for inserting an indwelling needle ~~in~~of the present application is applied not only to dialysis, but also to regular tests (blood sampling, etc.) or

chemical grouting (fluid infusion, etc.), which is carried out continuously or discontinuously. The hole-forming pin for inserting an indwelling needle can be used with a diameter of from 0.5 mm to 2.0 mm for ~~the~~-needles for blood examination having ~~the-a~~ diameter of from 0.5 mm to 1.8 mm, or for ~~the~~-needles for fluid infusion having ~~the-a~~ diameter of from 1.0 mm to 1.5 mm as needed. The length of the hole-forming pin for inserting an indwelling needle in-of the present application is preferably from 3 to 20 mm, since the distal end of the pin can reach a wall of the blood vessel or a position close to the blood vessel in placing the hole-forming pin.

In the hole-forming pin for inserting an indwelling needle according to the present invention, elastic deformation of ~~a-an~~ elastic joint is such that the entire wings can be moved in ~~the-a~~ direction of a right angle cross-section which is substantially at a right angle to blood flow direction of the blood vessel to which the column-shaped insertion part is to be inserted with respect to the insertion stop part.

By this, since Since the insertion part and the wings are flexibly connected via the elastic joint ~~part-sparts~~, opening and closing of the wings and the insertion operation are good because they can be easily performed. Therefore, operability of the insertion can be easily performed. Since the fixing force of the wings transmitted to the insertion part is relaxed in fixing the pin and the load for the living body can be preferably reduced, it is preferable to flexibly connect the wings via the elastic joint parts-flexibly.

In the hole-forming pin for inserting an indwelling needle of the present invention, elastic deformation at the elastic joint parts allows the column-shaped insertion part to have flexibility in the puncturing angle to the blood vessel with respect to the wings. In this case,

even when the angle of the puncture passage (button hole) after having removed the indwelling needle and the angle of puncture of the hole-forming pin are not exactly the same, the pin can be inserted smoothly along the angle of the button hole by inserting the insertion part therethrough.

5 In the pin for forming a hole for inserting an indwelling needle according to the present invention, elastic deformation at the elastic joint allows the column-shaped insertion part at the insertion stop part to have angular flexibility substantially in the rotating direction about the axis of the column-shaped part of the column-shaped insertion part with respect to the wings.

10 In this case as well, even when the puncture passage after having removed the indwelling needle is formed not exactly above-in the direction of the blood vessel, but is formed slightly obliquely toward the blood vessel, the hole-forming pin can be inserted smoothly and, even the insertion operation can be performed without increasing the load exerted on the living body.

15 In the hole-forming pin for an-inserting an indwelling needle according to the present application, when the elastic deformation at the elastic joint is set based on the material and the shape of the elastic joint parts so that the balance with the elastic deformation for allowing the column-shaped insertion part to have flexibility in the puncturing angle to the blood vessel with respect to the wings and the elastic deformation
20 for allowing the column-shaped insertion part at the insertion stop part to have angular flexibility substantially in the rotating direction about the axis of the column-shaped part of the column-shaped insertion part –with respect to the wings are respectively adjusted

respectively, even when the angle of the insertion part does not exactly match the puncture passage after having removed the indwelling needle, the insertion part of the hole-forming pin can be inserted smoothly along the button hole as long as both of the aforementioned angles are within ~~the~~an angular error on the order of ± 2 to 10° –for each direction.

5 Then, when the pin for forming a hole for inserting an indwelling needle of the present invention is configured in such a manner that the wings are connected to the insertion stop part via flexible joint branches, ~~the~~a hole-forming pin having superior operability with suitably balanced angular flexibility in terms of the puncturing angle with respect to the blood vessel to which the column-shaped insertion part is inserted and of the
10 angle at which the insertion stop part in association with the column-shaped insertion part substantially rotates about the axis of the column-shaped part –of the column-shaped insertion part –can be obtained, and the load exerted to the living body can be minimized.
Among others, in view of practicability, the dimensions of the joint branches are most
preferably from 0.1 to 2 mm in diameter of the lateral cross-section, and 0.5 to 10 mm in
15 length.

The term "joint branch" is an appellation of an embodiment of the elastic joint part which ~~connect~~connects the insertion stop part and the wings of the pin for forming a hole for installing an indwelling needle, and represents the part extending from the insertion stop part in a branch shape and connecting the insertion stop part and the wings.

20 The jig for installing used for the pin for forming a hole for inserting an indwelling needle of the present invention is a jig for installing the above-described hole-forming pin from the skin surface toward the blood vessel ~~including~~and ~~includes~~ supporting means

having a main body and a sliding body that is built in-into the main body for sliding in the longitudinal direction of the main body, the supporting means supporting the hole-forming pin at the distal end(s) of the main body and/or the sliding body. Therefore, it is preferable to use the jig for installing the hole-forming pin for inserting an indwelling needle, since there is no uncertainty of installation such as is the case of inserting with fingertips, and insertion with smoothness and mounting of the hole-forming pin along the button hole can be achieved with smooth installing-installation of the hole-forming pin from the skin surface to the blood vessel, which are-is supported by the support means by moving the slide part built in-into the main body.

The jig for installing the hole-forming pin according to the present invention comprises two opposite side-plates extending in parallel with the main body, and which are formed integrally in the main body. The sliding body can slide forwardly of the main body with a guide that engages the inner walls of the two side plates which constitute the main body and the outer wall which constitutes the sliding body, or comprise the two spring parts bending in the outward direction of the main body and the sliding body, the two spring parts are-being respectively fixed at the ends thereof to the left and right side walls of the main body and the left and right side walls of the sliding body, wherein the sliding body is inserted slidably into a sliding shaft projecting from the distal end of the main body.

The forwardly-distal end of the main body of the jig for installing represents the side on which the pin for forming a hole for inserting an indwelling needle is attached and the forming pin is loaded from the skin surface toward the blood vessel.

It is preferable to use the jig for installing the pin of the present invention wherein

the sliding body is provided with driving means which allows the sliding body to slide easily along the main body with a smooth sliding movement—enabled, a finger hook part formed on a part of the sliding body is used as the driving means for the sliding body due to its simple operationalityway of operating.

- 5 Since the easier and stable operability can be preferably obtained by employing a form—an embodiment in which the energizing force of thea spring is utilized for the sliding movement caused by pressing the finger stop part, a constant operating force which does not vary depending on the individual difference of thean operator like a finger movement, it is preferable to use the jig for installing the pin of the present invention, wherein the
- 10 driving means for the sliding body is built ininto the tubular main body formed of left and right side walls, a bottom plate, a top plate and a rear end wall; a coil spring is fitted between the interior of —the rear end wall of the main body and the rear end of the sliding body so that the sliding body is energized forward; an upper part of the sliding body is formed with an inclined plane facing a forwardly; a—an inclined plane facing rearwardly
- 15 corresponding to said inclined plane is formed on the lower part —of the finger hook part, and the upper part of the finger hook part projects above the main body through a through-hole formed on the top plate of the main body.

When the jig for installing the pin according to the present application is configured in such a manner that at least one part of the supporting means for supporting the

20 hole-forming pin is moved relatively backward of the distal end of the main body, and the jig has a good operability since the hole-forming pin can be fixed to the skin surface with adhesive tape via the wings by immediate separation of the jig, which is not necessary any

longer for operation, from the hole-forming pin after the hole-forming pin is inserted from the skin surface toward the blood vessel.

When the jig for installing the pin according to the present application is formed with wing holding means for holding the wings of the pin for forming a hole for inserting
5 an indwelling needle at the distal end of the main body and/or the distal end of the sliding body, the distal end of the hole-forming pin is prevented from being unstable in direction because the wings of the hole-forming pin are swung over during the mounting operation, and hence the hole-forming pin can be reliably inserted in the predetermined direction, thereby achieving good operability.

10

Brief Description of the Drawings

Fig. 1 is a perspective view of one embodiment of the present invention of a pin for forming a hole for inserting an indwelling needle. A pin A for forming a hole for inserting an indwelling needle A-comprises a column-shaped insertion part 1 having a curved surface at the distal end, an insertion stop part 2 provided on the proximal end of the insertion part 1, and wings 4 connected to the insertion stop part 2 via elastic joint parts 30. In this embodiment, as a best form for implementing the present invention, a case in which the elastic joint parts 30 is-are formed with a joint branches-branch 3 extending from the insertion stop part, and which is a thin and flexible part formed into a branch shape for connecting the insertion stop part and the wings, is described.
15
20

Fig. 2 is a perspective view showing another embodiment of the pin for forming a hole for inserting an indwelling needle according to the present invention, showing an

example of the embodiment of the elastic joint parts 30 and the action of the wings 4 whose motion is facilitated thereby.

Fig. 3 is a perspective view for explaining followability to the puncture passage when the pin for forming a hole for inserting an indwelling needle of the present invention 5 is applied.

Fig. 4 to Fig. 8 show a jig for installing the pin used for the pin for forming a hole for inserting an indwelling needle of the present invention. A jig B comprises a main body 6, and a sliding body 7 built in the main body 6 for sliding in the longitudinal direction. The sliding body 7 can be slid easily by driving means 9, and a supporting means 10 for supporting the pin for forming a hole for inserting an indwelling needle A for ~~holding the indwelling needle from the skin surface to the blood vessel~~ is provided on the distal end of the main body 6 and/or the sliding body 7.

Fig. 4 to Fig. 8 show ~~thee~~three examples for explaining the embodiments respectively in which (a) shows a state in which the pin for forming a hole for inserting an indwelling needle is attached to the jig, and (b) shows a state in which the pin for forming a hole for inserting an indwelling needle is separated from the supporting means of the jig (that is, ~~the state after having loaded the hole forming pin~~) respectively in Fig 5, Fig 6 and Fig 8. Fig. 4 is an exploded view of Fig. 5, and Fig. 7 is an exploded view of Fig. 8.

20 Best Mode for Carrying Out the Invention

Hereinafter referring now to the drawings, the pin for forming a hole for inserting an indwelling needle according to the present invention and the jig thereof will be

concretely described based on examples.

(EXAMPLE 1)

First, the actions in each component of the pin A for forming a hole for inserting an
5 indwelling needle A in the present invention will be described.

Fig. 2 shows an example of the embodiment of the pin for forming a hole for
inserting an indwelling needle according to the present invention. An insertion stop part 2 is
provided at the proximal end of a column-shaped insertion part 1, and wings 4 are
connected to both sides of the insertion stop part 2 via elastic joint parts 30. Since the
10 elastic joint parts 30 are provided with higher flexibility than other parts of the
hole-forming pin such as the insertion stop part 2 or the wings 4, the wings 4 can be erected
to the insertion stop part 2 as shown by a broken line in the drawing by easy bending of the
wings formed in a flat state as shown in the drawing.

As described above, the wings 4 standing upright ~~is held~~are held with fingertips,
15 the column-shaped insertion part 1 of the pin for forming a hole for inserting an indwelling
needle is inserted into a puncture passage after having removed the indwelling needle, then
the wings 4 restored into the flat state again can be fixed by taping from above with
adhesive tape or the like.

In addition, in order to provide higher flexibility to the elastic joint parts 30 than the
20 wings 4, the manner such as designing the length of the elastic joint parts 30 (w_2 in the
drawing) shorter than the width (w_1 in the drawing) of the wings 4, providing elastic joint
parts 30 formed with a partly thinned part as shown in Fig. 2(a), or employing a soft

material only for the elastic joint parts 30 as shown in Fig. 2(b) can be used.

In the case of puncturing a needle into a blood vessel, the needlepoint is punctured generally at a suitable angle with respect to the direction of the blood vessel. However, the column-shaped insertion part 1 of the pin for forming a hole for inserting an indwelling

5 needle cannot be necessarily oriented exactly at the angle of the puncture passage after ~~having removed~~ the indwelling needle has been removed, but and in general there arises a certain error in the angle.

Then, Fig. 3 shows angles for permitting the flexibility required for the followability to the puncture passage to be given to the column-shaped insertion part 1 of the pin for 10 forming a hole for inserting an indwelling needle

In other words, $a-\alpha$ shows flexibility of the puncturing angle of longitudinally-in the longitudinal direction of a blood vessel 5, and $b-\beta$ shows flexibility of the angle in the circumferential direction of the axis of the column-shaped part of the column-shaped insertion part of the insertion stop part substantially, respectively.

15 These flexibilities of angles that are $a-\alpha$ and $b-\beta$ in two directions must be provided based on the material or shape of the elastic joint parts 30 so as to adjust the balance in elastic deformation in the respective directions.

It is preferable that the range of the error in angle is adjusted practically within the range of about ± 2 to 10° , with a determination by the form, material, and dimensions of the 20 elastic joint parts 30 of the pin for forming a hole for inserting an indwelling needle, whereby a smooth insertion operation is achieved.

In addition, when the error in angle exceeds the max value of $\pm 10^\circ$, the flexibility

of the angle becomes too much, and the insertion angle of the column-shaped insertion part 1 becomes unstable, and usability becomes hard by the deterioration of operability.

In contrast, when the error in angle is ~~below~~below $\pm 2^\circ$, it is too tough for adjustment, and hence it is not suitable for practical use.

5 The practical selection of the elastic joint parts 30 based on the material or shape is done after making a study of the length W2 as shown in Fig. 2 as an example, thickness, or elasticity depending on the cross-sectional shape or the types of material.

(EXAMPLE 2)

10 Referring now to Fig. 1, an example set-as a preferred embodiment as described above will be described. In this embodiment, the insertion part 1 is formed by injection molding using a low-density polyethylene.

15 In the pin for forming a hole for inserting an indwelling needle shown in Fig. 1, a column-shaped insertion part 1 has a shape having a curved, or rounded, surface at the distal end thereof.

With this shape, when forming a button hole by inserting the insertion part 1 to a part punctured by a dialysis indwelling needle or the like, the possibility to ~~give damages to~~ damage a wall or other parts is eliminated.

20 In order to form a hole having a size that can accept the indwelling needle with a non-sharp distal end, the outer diameter of the insertion part 1 is preferably from 0.5 to 3.0 mm, and more preferably from 1.0 to 2.0 mm, ~~although the application of the indwelling needle described above~~.

The length of the insertion part 1 is preferably from 3 to 20 mm, and more preferably, from 4.0 to 6.0 mm so that the distal end of the pin can reach a wall of the blood vessel or a position close to the blood vessel in placing the hole-forming pin for the indwelling needle.

5 Although the insertion part 1 is generally inclined by a suitable angle corresponding to the puncturing angle of the indwelling needle, the present invention is not limited thereto, and the insertion part 1 may be provided perpendicularly to the wings 4. In this embodiment, the entire body is provided by integral molding, and each of the wings 4 is formed to be 10 mm square, and 1 mm in thickness.

10 The material for forming the insertion part 1 may be a synthetic resin such as polyurethane, polypropylene, polycarbonate, ABS resin, polyethylene, polytetrafluoroethylene, and polysulphone or a metal such as stainless steel and the like. Materials coated by antithrombotic material or antibacterial material are preferably used, and those materials mixed into the synthetic resin are also preferably used in the case of
15 using the synthetic resin.

The insertion stop part 2 is provided for preventing the insertion part 1 from immersing embedding completely into the skin, and preventing the formation of the entrance of the buttonhole from becoming incomplete.

20 The shape of the insertion stop part 2 can be employed as a spherical shape, plate shape, conical shape, egg-shape or the like. The cross-sectional shape of the insertion stop part 2 in the horizontal direction (in the direction in-parallel with the surface of the skin which comes into contact therewith) may be any shape as long as there is a part larger than

the outer diameter of the insertion part 1 (in the part of maximum diameter). For example, in a circular plate, the maximum diameter is preferably from 2 to 10 mm, and more preferably, from 3.0 to 5.0 mmΦ.

In the example of the embodiment of the pin for forming a hole for inserting an
5 indwelling needle according to the present invention shown in Fig. 1, joint branches 3 are
employed as parts which are adjusted in balance in elastic deformation in directions within
a-α and b-β respectively. As described above based on Fig. 3 as one form of the elastic joint
parts 30, a-α shows flexibility of the puncturing angle longitudinally of the blood vessel 5,
and b-β shows angular flexibility of the column-shaped insertion part at the insertion stop
10 part substantially in the rotating-rotational direction about the axis of the column-shaped
part.

In other words, the joint branches 3 are parts that connect the insertion stop part 2
and the wings 4, and have a certain degree of flexibility. Accordingly, when there is a
difference between the angle of the insertion part 1 to the wings 4 and the angle of the
15 wound (passage) which is a previous stage of a hole to be formed in a state in which the
wings 4 described later are fixed to the skin, fine adjustment such as to absorb the
difference is effected by twisting of the joint branches 3, so that no load is applied to the
living body.

As described above, in order to provide the joint branches 3 ~~to have a~~with suitable
20 flexibility to the insertion stop part 2 or the wings 4, a preferable combination of thickness,
length, and material is set. When the insertion part 1 is formed by injection molding of
low-density polyethylene and is circular in lateral cross section of the insertion part 1 as in

the present embodiment, the diameter is preferably from 0.5 to 3 mmΦ and more preferably from 1 to 2 mmΦ, and the length is preferably from 0.5 to 10 mm, and more preferably from 1 to 5 mm.

The wings 4 work as fixing means for fixing the insertion part 1 tightly to the skin surface. In the case of the pin for forming a hole for inserting an indwelling needle in the prior art, it is necessary to attach a separate auxiliary part-device to a holding part (recess) formed on the insertion stop part before insertion, and to then remove the auxiliary device again after insertion. However, in the case of the pin for forming a hole for inserting an indwelling needle of the present invention, since the operator can hold the wings 4 with fingertips, insert the insertion part 1 and fix the pin without modification, an indwelling operation can be performed easily. In this case, it is preferable for medial personnel also to wear medical gloves or the like of plastic film so as to prevent infection and maintaining to maintain an aseptic condition.

As the shapes of the wings 4, a polygonal shape such as a triangle or square, the and shapes including a curved line, such as a circular shape, oval shape, or egg shape may also be employed in addition to the pentagonal shape shown in Fig. 1. Then, the area of each wing 4 is preferably from 20 to 500 mm², and more preferably from 50 to 200 mm², since the wing is required to have dimensions that make it possible to hold the wings easily in inserting when the pin is inserted by an operator, to fix the wings to the arm or the like, and not to not give any load in fixing.

From the viewpoint of minimizing the adhered area of the tape on the skin, it is also possible to cut off one of the two wings 4 shown in the drawing when the insertion part 1 is

inserted and to adhere the tape ~~may adhere on to~~ the remaining wing 4. In this case, since the joint branches 3 are provided with a thinned part having flexibility, one of the two wings 4 can easily be cut off.

In the case of the pin for forming a hole for inserting an indwelling needle
5 according to the present invention, the insertion part 1, the insertion stop ~~part~~part 2, the joint branches 3 and the wings 4 are generally formed integrally by injection molding in view of production cost. However, it is also possible to form the insertion part 1 separately, and add the insertion part 1 to ~~the~~an insertion stop part 2 that is formed integrally with the wings 4. The material for the insertion stop ~~part~~part 2, the joint
10 ~~branch~~branches 3, and the wings 4 in this case may be the same material used for the insertion part 1, and a soft material such as ~~the~~ flexible polyvinyl chloride, or a rubberlike elastic body can be used as the material.

(Example 1 of the jig for installing the pin)

15 In Fig. 4 (and Fig. 5) showing a first embodiment of a jig B for installing the pin B ~~used for the pin A~~ for forming a hole for inserting an indwelling needle according to the present invention, the jig B comprises a main body 6 and a sliding body 7 built into the main body 6, which slides in the direction of length of the main body 6.

20 In this embodiment, supporting means 10 for supporting the pin A for forming a hole for inserting an indwelling needle A are provided at the distal end of the sliding body 7. The main body 6 is formed integrally by connecting two parallel opposing side plates 61 at

rear ends thereof. The guides Guides 62 are formed on the inner walls of the two side plates 61, respectively. The guides Guides 72 ~~is~~^{are} also formed on the outer walls 71 on the left and right sides which constitute the sliding body 7 to be inserted between the two side plates 61. The guides 62 and the guides 72 engage in the sliding direction so that the 5 sliding body 7 can be slidable toward the front of the main body 6. A finger stop 91 ~~are~~^{is} formed as driving means 9 at the upper part of the sliding body 7, and the sliding body 7 is adapted to be slid by fingers holding the main body 6.

In this first embodiment, since a gap formed between the distal end of the main body 6 and the distal end of the sliding body 7 serves as a wing holding means 100 for 10 holding the wings 4 in a state in which the pin for forming a hole for inserting an indwelling needle shown in Fig. 5 is attached to the jig B for installing the pin B, the pin A for forming a hole for inserting an indwelling needle A before mounting is fixedly attached to the distal end of the jig B without swinging of the two wings 4, and the direction of the hole-forming pin becomes stable. The hole-forming pin can be reliably inserted in the 15 predetermined direction; therefore, operability of the jig is good.

(Example 2 of the jig for installing the pin)

In Fig. 6 showing a second embodiment of the jig B used for the hole-forming pin of the present invention, the sliding body 7 is slidably inserted into a sliding shaft 63 projecting from the distal end of the main body 6. The ends of two expandible arm-shaped spring parts 8 bent in the outward direction of the main body 6 and the sliding body 7 are fixed to the left and right side walls 61 of the main body 6 and the left and right side walls

71 of the sliding body 7, respectively. The spring parts 8 become bendable by using pin connecting parts 81 to cause the sliding movement of the sliding body 7 by the difference of the distance between the both ends of the spring parts 8, which ~~are~~is generated by expansion and contraction of the spring parts 8. Finger stop parts 91 ~~is~~are formed in the 5 pin connecting part 81 of the spring part 8 as the driving means 9, and the sliding body 7 is adapted to slide with respect to the sliding shaft 63 by pushing the left and right finger stop parts 91 with fingertips.

In the second embodiment, the distal end of the sliding shaft 63 projecting from the distal end of the main body 6 is fitted into an insertion hole 21 (not shown in the drawing) 10 formed on the opposite side from the projecting side of the insertion part 1 of the insertion stop part 2 of the pin for forming a hole for inserting an indwelling needle A and works as the supporting means 10 for supporting the pin for forming a hole for inserting an indwelling needle.

15

The supporting means 10, in other ~~word~~words, the distal end of the sliding shaft 63 in this case, is moved relatively backward to the sliding body 7 in association with the above-described sliding movement, whereby the pin for forming a hole for inserting an indwelling needle is separated from the supporting means 10. Accordingly, the jig can be 20 removed immediately after inserting the hole-forming pin from the skin surface toward the blood vessel. Therefore, ~~the~~an operation such as to remove the hole-forming pin from the jig with other medical jigs or the like is not necessary, and the hole-forming pin can be

fixed to the skin surface immediately with the wings by adhesive tape or the like, thereby achieving good operability.

(Example 3 of the jig for installing the pin)

5 In Fig. 7 (Fig. 8) showing a third embodiment of the jig B used in the hole-forming pin according to the present invention, the jig B comprises a main body 6 and the sliding body 7 that is built in the main body 6 and slides in the longitudinal direction of the main body 6, the main body 6 being tubular shape having left and right side walls 65, a bottom wall 66, a top plate 67, and a rear end wall 68. A coil spring 90 is fitted between the inside 10 of the rear end wall 68 of the main body 6 and the rear end 74 of the sliding body 7 so that the sliding body 7 is energized to the front. The sliding body 7 is formed with a forwardly facing inclined surface 73 on an upper part thereof, a rearwardly facing inclined surface 93 corresponding to the forwardly facing inclined surface 73 is formed on the lower part of the finger stop part 92, and the upper part of the finger stop part 92 projects upwardly of the 15 main body 6 through a through hole 64 formed on-in the top plate 67 of the main body 6. Then, when the finger stop part 92 is pressed downward, the rearwardly facing inclined surface 93 presses the forwardly facing inclined surface 73 of the sliding body 7, so that the sliding body 7 is slid rearwardly of the main body 6 in the compression direction of the coil spring 90.

20 At the front end of the sliding body 7, two wing supporting pins 75 connected to the front end of the sliding body 7 project obliquely forwardly of the main body through the through holes 64' formed at the front end of the main body 6, and the distal ends of the

wind-wing supporting pins 75 are fitted into two small holes 41 formed on the wings 4 of the pin A for forming a hole for inserting an indwelling needle-A. The front end has a function as the supporting means 10 that support-supports the hole-forming pin A and simultaneously, a function as the wing holding means 100 for holding the wings 4. As in 5 the case of the second embodiment described above, the supporting means 10 moves, relatively backward to the main body 6 when the sliding body 7 slides, and the wing supporting pins 75 are retracted from the through holes 64' formed at the distal end of the main body 6 to separate the pin A for forming a hole for inserting an indwelling needle A from the supporting means 10 so that the jig B can be separated immediately after having 10 inserted the hole-forming pin A from the skin surface toward the blood vessel.

As the material of the above-described jig B, an injection-molded product of a thermoplastic synthetic resin can be used for the finger stop part and the pins supporting a wing part, as well as the main body, and the sliding body generally, but a cast product of an alloy, cut product of metal, and the like also can be used. Also, the spring material for the 15 expandible arm-shaped spring may be preferably formed of a corrosion-resisting metal material, and the-a coil spring formed of corrosion-resistant metallic wire material such as stainless steel is used.

Industrial Applicability

20 The usage of the pin for forming a hole for inserting an indwelling needle of the present invention will be described first. First, the-a process of dialysis or the like starts by puncturing the dialysis-indwelling needle having a sharp edge into a vein of a patient.

The dialysis-indwelling needle is pulled out after the process of the hemodialysis is completed. Since a passage is formed as a puncture passage immediately after having removed the dialysis-indwelling needle, the hole-forming pin according to the present invention is inserted along the passage.

5 By removing the hole-forming pin which is indwelt for several days ~~with~~by fixing the wings 4 to the arm with adhesive tape, an indwelling needle insertion hole (button hole) extending from the skin surface to the interior of the blood vessel is formed to the wall of the blood vessel or to the position close to the blood vessel.

Therefore, for the next treatment, by puncturing the wall of the blood vessel with the
10 puncturing needle only once in this point, the passage is pierced from the skin surface to the interior of the blood vessel.

When it is not used, the buttonhole is clogged by blood that is a solid-state or semi-solid and slough is formed on the surface of the entrance of the buttonhole.

Therefore, when the dialysis-indwelling needle indwells in the buttonhole, the slough is
15 removed with a medical hook or tweezers so that the indwelling needle can be inserted into the hole. As the dialysis-indwelling needle to be inserted into the buttonhole, ~~the~~ one whose distal end is not sharp is preferably selected, whereby it causes the patient less pain.

As described above, with the pin for forming a hole for inserting an indwelling needle, even when the angle of the puncture passage which appears following the removal
20 of the indwelling needle and the angle of the hole-forming pin are not necessarily identical, the insertion part can be inserted smoothly along the angle of the puncture passage owing to flexibility of the elastic joint parts provided on the pin for forming a hole for inserting an

indwelling needle. Since the pin for forming a hole for inserting an indwelling needle does not rotate while it is indwelling, the buttonhole can be formed in an intended direction and angle.

5 Since the button hole, which ~~become an~~ becomes a passage to be inserted for inserting the indwelling needle, can be easily formed by the pin for forming a hole for inserting an indwelling needle in the present invention, during indwelling of the indwelling needle, the burden to the living body can be alleviated. During dialysis by the buttonhole method, the burden to the living body also can be alleviated.

10 Furthermore, since by holding the wings can perform the insertion into the puncture ~~can be performed~~, the insertion operation is easy even without using the jig. When the jig is used for mounting the hole-forming pin as required, with the jig for installing the hole-forming pin according to the present invention, the hole-forming pin can be attached reliably to the jig, and the jig can be used while confirming the direction of insertion into the living body.

15 The jig for installing the pin can be removed immediately after inserting the hole-forming pin from the skin surface toward the blood vessel. Therefore, the operation such as to remove the hole-forming pin from the jig with other medical jigs or the like is not necessary, and the hole-forming pin can be fixed to the skin surface immediately with the wings by adhesive tape or the like, thereby achieving good operability.

20 The hole-forming pin for inserting ~~the-a~~ dialysis indwelling needle has been described in the description of the embodiment above, but the pin for forming a hole for inserting an indwelling needle of the present application is widely applied not only to ~~the~~

dialysis, but also ~~the-to~~ applications such as regular inspection such as blood sampling or continuous or discontinuous administration of drug solution (such as fluid infusion) in accordance with the intended use depending on the setting of the material or dimensions of the inserting part –of the indwelling needle hole-forming pin or of the elastic joint part .